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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,965	KORNACKER, MICHAEL G.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

I. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-5, in so far as they are drawn to an isolated nucleic acid sequence, classified in class 435, subclass 69.1.
2. Claim 6, drawn to an isolated polypeptide sequence, classified in class 530, subclass 300.
3. Claims 7-8, in so far as they are drawn to a polypeptide complex comprising a P2Y-type GPCR and a peptide, classified in class 530, subclass 350.
4. Claims 9-10, in so far as they are drawn to an antibody, classified in class 530, subclass 387.1.
5. Claim 11, drawn to a method of isolating polypeptide comprising incubating a polypeptide of amino acid sequence as recited in claim 11, with an antibody that binds to the peptide and isolating the said peptide, classified in class 435, subclass 7.1.
6. Claim 12, drawn to a peptide library generated from an isolated nucleic acid sequence, classified in class 530, subclass 300.

7. Claims 13 -14, drawn to a method of identifying a binding agent for a P2Y-type GPCR comprising screening a peptide library generated for one or more peptide, classified in class 435, subclass 7.1.

8. Claim 15, drawn to a method of identifying a P2Y-type GPCR comprising incubating a polypeptide, an antibody that binds the said polypeptide with a biological sample under condition suitable for the peptide or antibody to bind to a GPCR, classified in class 435, subclass 7.1.

9. Claim 16, drawn to a method of identifying a binding agent for a P2Y-type GPCR comprising incubating an isolated protein complex comprising a P2Y-type GPCR and a peptide; with a test agent under a condition suitable for the binding of said test compound and measuring the dissociation of polypeptide complex, classified in class 435, subclass 7.1.

10. Claim 17, drawn to a method of identifying a binding agent for a P2Y-type GPCR comprising incubating a GPCR with a test agent and then incubating with an isolated polypeptide, and measuring the complex formation between the receptor and a polypeptide, classified in class 435, subclass 7.1.

11. Claim 18, drawn to a kit for detecting a P2Y-type GPCR comprising an isolated peptide, an antibody that binds the peptide, and one or more reagents for the detection of binding between the receptor and the peptide or antibody, classified in class 435, subclass 7.1.

12. Claim 19, drawn to a method of diagnosing a proliferative disorder comprising incubating an isolated polypeptide as recited in claim 6, and an antibody that binds the peptide; with a biological sample under a suitable condition that allows said peptide or said antibody to associate with a P2Y-type GPCR and measuring the level of said peptide-receptor or antibody –receptor complex formation, classified in class 435, subclass 7.1.

13. Claims 20-21, drawn to a pharmaceutical composition comprising an isolated nucleic acid as recited in claim 1 or a vector comprising an isolated nucleic acid sequence of claim 1, and a method of treating a proliferative disorder comprising administering a pharmaceutical composition comprising a nucleic acid, classified in class 514, subclass 44.

14. Claim 20, drawn to a pharmaceutical composition comprising a polypeptide, classified in class 514, subclass 12.

15. Claim 20, drawn to a pharmaceutical composition comprising an antibody, classified in class 424, subclass 130.1.

16. Claim 21, drawn to a method of treating a proliferative disorder comprising administering a pharmaceutical composition comprising a polypeptide, classified in class 424, subclass 9.1.

17. Claim 21, drawn to a method of treating a proliferative disorder comprising administering a pharmaceutical composition comprising an antibody, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1, 2,3, 4, 6, 11, 14 and 15 are patentably distinct products.

Inventions 1 and 2 are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polypeptide of Group 2 and the polynucleotide of Group 1 are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group 1 does not necessarily encode the polypeptide of Group 2.

Furthermore, searching the inventions of Groups 1 and 2 together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of Groups 1 and 2 have a separate status in the art as shown by their different classifications. In cases such as this one

where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. Furthermore, a search of the nucleic acid molecules of Group 1 would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of Group 2. As such, it would be burdensome to search the inventions of Groups 1 and 2.

The polypeptide of Group 2, the polypeptide complex of Group 3, the antibody of Group 4, and the polypeptide library of Group 6 are patentably distinct for the following reasons:

While the inventions of Groups 2, 3, 4 and 6 are polypeptides, in this instance, the polypeptide of Groups 2, 4 and 6 are single chain molecules, the polypeptide complex of Group 3 comprises a P2Y-type GPCR and a polypeptide of Group 2, whereas the polypeptide of Group 4 encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of Group 2 and 6, and the antibody of Group 4 are structurally distinct molecules; any relationship between a polypeptide of

Group 2, 6 and an antibody of Group 4 is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

In this case, the polypeptide of Group 2 is a large molecule which contains potentially hundreds of regions to which an antibody must bind, the polypeptide complex comprises a GPCR and a polypeptide, and the polypeptide of Group 6 is a representative collection of small polypeptides that are generated in a random fashion and has 100% identity to a polypeptide against it is generated. Whereas the antibody of Group 4 is defined in terms of its binding specificity to a polypeptide against it has been generated. Thus, immunization with the polypeptide of Group 2 would result in the production of antibodies outside the scope of Group 4. Therefore, the polypeptides of Group 2, the polypeptide complex of Group 3, the peptide library of Group 6, and antibodies of Group 4 are patentably distinct.

Furthermore, searching the inventions of Groups 2, 3, 4 and Group 6 would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide, a library comprising various polypeptides, and an antibody require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group 4. Furthermore, antibodies which bind to an epitope of a polypeptide of Group 2 may be known even if a polypeptide of Group 2 is novel. In addition, the technical literature search for the polypeptide of Group 2, 6 and the antibody of Group 4 is not coextensive,

e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target and a peptide library can be made either by polypeptide fragmentation, by direct peptide synthesis or by expressing polynucleotides encoding the polypeptides.

The kit of Group 11 and an antibody of Group 4 are patentably distinct for the following reasons:

The kit of Group 11 comprises a polypeptide, an antibody of Group 4 that binds to the polypeptide and other necessary reagent for the detection of binding between antibody, and the polypeptide. Thus, an antibody of the kit is only a component of the whole kit. Therefore, the kit of Group 11 and antibodies of Group 4 are patentably distinct. Furthermore, searching the inventions of Group 4 and Group 11 would impose a serious search burden. The inventions have a separate status in the art and as such the search for an antibody and a kit is not coextensive.

The pharmaceutical compositions of groups 13 and 14 are patentably distinct for the following reasons:

In this case, the pharmaceutical composition of Group 13 comprises polynucleotide where is the pharmaceutical compositions of Group 14 comprises a polypeptide. The invention of Group 13 is directed to a gene therapy and it requires delivery methods that are different from the one for a pharmaceutical composition comprising a polypeptide.

Further, searching a pharmaceutical composition comprising a polynucleotide and a pharmaceutical composition comprising a polypeptide together would impose undue search burden and as such searches for a pharmaceutical composition comprising a polypeptide and a polynucleotide are not coextensive.

The pharmaceutical compositions of groups 14 and 15 are patentably distinct for the following reasons:

In this case, the pharmaceutical composition of Group 14 comprises polypeptide whereas is the pharmaceutical composition of Group 15 comprises an antibody. Though the inventions of both Group 14 and Group 15 comprise polypeptides; they are different from each other as described supra. Further, a composition comprising an antibody and a composition comprising a polypeptide require different component and they work differently.

Further, searching a pharmaceutical composition comprising an antibody and a pharmaceutical composition comprising a polypeptide together would impose undue search burden and as such searches for a pharmaceutical composition comprising an antibody and a pharmaceutical composition comprising a polypeptide are not coextensive.

Inventions 5, 7, 8, 9,10, 12, 16 and 17 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). The instant specification does not disclose that these methods would be used together. The method of isolating polypeptide comprising incubating a polypeptide of amino acid sequence as recited in claim 11, with an antibody that binds to the peptide and isolating the said peptide (group 5), the method of identifying a binding agent for a P2Y-type GPCR comprising screening a peptide library generated for one or more peptide (group 7), the method of identifying a P2Y-type GPCR comprising incubating a polypeptide, an antibody that binds the said polypeptide with a biological sample under condition suitable for the peptide or antibody to bind to a GPCR (group 8), the method of of identifying a binding agent for a P2Y-type GPCR comprising incubating an isolated protein complex comprising a P2Y-type GPCR and a peptide; with a test agent under a condition suitable for the binding of said test compound and measuring the dissociation of polypeptide complex (group 9), the method of identifying a binding agent for a P2Y-type GPCR comprising incubating a GPCR with a test agent and then incubating with an isolated polypeptide, and measuring the complex formation between the receptor and a polypeptide (group 10), the method of diagnosing a proliferative disorder comprising incubating an isolated polypeptide as recited in claim 6, and an antibody that binds the peptide; with a biological sample under a suitable condition that allows said peptide or said antibody to associate with a P2Y-type GPCR and measuring the level of said peptide-receptor or antibody –receptor complex formation (group 12), the method of treating a proliferative disorder comprising administering a pharmaceutical composition comprising a polypeptide (group 16) and the method of treating a proliferative disorder comprising administering a pharmaceutical composition

comprising an antibody (group 17) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Therefore, each method is divergent in materials and steps. For these reasons the Inventions 5, 7, 8, 9,10, 12, 16 and 17 are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups 5, 7, 8, 9,10, 12, 16 and 17 have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups 5, 7, 8, 9,10, 12, 16 and 17 together.

Inventions 2 and 16 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case polypeptide of Group 2 can be used for producing an antibody for immuno-assays.
Searching the inventions 2 and 16 together would impose undue search burden. The inventions of 2 and 16 have a separate status in the art as shown by their different classifications. Moreover, the search for a polypeptide and the methods of using a polypeptide for a method of treating a disease are not coextensive.

Inventions 4 and 5/7/12 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case an antibody of Group 2 can be used for purifying the polypeptide using affinity chromatography. Searching the inventions 4 and 5/7/12 together would impose undue search burden. The inventions of 4 and 5/7/12 have a separate status in the art as shown by their different classifications. Moreover, the search for an antibody and the methods of using an antibody for a method of treating a disease or a method of isolating a polypeptide or a method of diagnosing a proliferative disorder are not coextensive.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims

may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Further Restriction

II. If Group 1 is elected, a further restriction to one of the following inventions is required under 35 U.S.C. 121:

The invention Group 1 pertain to a number of nucleic acid sequences listed in claims 1- 5.

Each of the claimed nucleic acid sequences are composed of different purine and pyrimidine units and are structurally distinct molecules. Each sequence or gene requires a unique separate search of the prior art. Searching two claimed sequences or genes would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. Therefore, Applicant must choose 1 sequence or gene from the group against which the search should be performed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

III. If Groups 2 or 3 is elected, a further restriction to one of the following inventions is required under 35 U.S.C. 121:

The inventions Groups 2 pertain to a number of polypeptide sequences listed in claims 6-7.

Each of the claimed polypeptide sequences are composed of amino acid units and are structurally distinct molecules. Each sequence requires a unique separate search of the prior art. Searching two claimed sequences would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. Therefore, Applicant must choose 1 sequence from the group against which the search should be performed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

IV. If Group 4 is elected, a further restriction to one of the following inventions is required under 35 U.S.C. 121:

The invention Group 4 pertain to a number of antibodies that binds to a specific sequence of the polypeptide listed in claim 6.

Each of the claimed antibody is composed of amino acid sequence that encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the antibodis of Group 4 are structurally distinct molecules.

Each antibody that binds to a specific sequence against the said antibody is raised, requires a unique separate search of the prior art. Searching for more than one antibody would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. Therefore, Applicant must choose antibody from the group against which the search should be performed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

A. P2Y type GPCR:

(i) P2Y10

(ii) HGPRBMY3

(iii) HGPRBMY11

(iv) HGPRBMY23

The species are independent or distinct because each P2Y-type GPCR is different polypeptide that could bind to a specific antibody or a polypeptide, which are different from each other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 8, 10, 14 are an example of generic claims.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If Applicant selects Group 3, 4 or 7, one species from P2Y type GPCR group must also be chosen to be considered fully responsive.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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19 July 2006
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